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(54) **CASING MEANS FOR ANALYTICAL TEST STRIP**

GEHÄUSE FÜR ANALYTISCHES TESTSTRIP

BOITIER POUR BANDE DE TEST ANALYTIQUE

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Description

[0001] This invention relates to the field of clinical diagnosis. More particularly, it relates to a casing useful in protecting a test strip and an analytical device comprising said casing and a test strip.

[0002] Clinical diagnosis relates, in general, to the determination and measurement of various substances which relate to the health or general status of an individual. Physicians, health care workers, and the general public as well are concerned about the presence and levels of various substances in body fluids such as blood, urine, and so forth. Among the substances which have been measured in clinical analysis for a long time are glucose, cholesterol, and various enzymes such as amylase and creatine kinase. More recently, determinations as to pregnancy, blood disorders ("Quick's" tests, Partial thromblastin time or "Ptt" tests, etc.), and infections have also become routine in clinical diagnosis. Of most pressing concern to the field, e.g., is the determination of antibodies to human immunodeficiency virus (HIV), as a marker for Acquired Immune Deficiency Syndrome ("AIDS") or Aids Related Complex ("ARC"). The new tests for this virus, however, build on a broad and deep base of earlier advances in the field.

[0003] An oversimplification which nonetheless serves to place the subject invention in proper context is division of the field into "wet chemistry" and "dry chemistry". The former pertains to methodologies where a reaction takes place completely in a liquid state. Exemplary of such chemistries is U.S. Patent No. 4,818,692, which describes an alpha amylase assay. Review of this reference shows that a reagent is added to a liquid sample, and, if the analyte of interest (amylase) is present, the reagent reacts with it, yielding a color. The development and intensity of the color are monitored as a determination of the presence and amount of the analyte ("Analyte" as used hereafter, in any context, refers to a substance to be determined). "Dry chemistry", in contrast, involves the placement of some or all of the reagents which are involved in determination of an analyte under consideration onto a solid material, such as a paper strip. The sample is brought into contact with the solid material, and some or all of the reactions which are necessary for the detection of the analyte in question take place in situ. If additional reactions involving reagents not found on the solid material are required, these can be added after the preliminary reactions take place. The invention concerns dry chemistry, and therefor wet chemistry is not discussed hereafter.

[0004] The art is filled with many different examples of dry chemistry apparatus used for clinical analysis. Examples of some of the patents in the field include U.S. Patent No. 4,446,232, to Liotta, 4,361,537 to Deutsch et al., and 4,861,711 to Friesen et al.

[0005] Liotta teaches a very simple example of a zoned test strip useful in immunodiagnostics. A support such as a paper strip, has enzyme linked antibodies positioned in the strip, as well as a reagent which can react with the enzyme label. When analyte for which the antibody is specific is contacted to the strip, the antibodies bind with the analyte and diffuse to the point in the strip where the substrate reagent is found. There, enzyme-substrate interactions take place resulting in a color forming reaction, indicating the presence of analyte in the sample.

[0006] If analyte is not present, then the conjugate is immobilized in the "solid phase" zone, preventing interaction of enzyme and substrate.

[0007] The Deutsch patent teaches a test strip which is contained in what is essentially a capped test tube. The test strip has various reagents positioned along its length. When liquid is introduced at one end of the strip, it moves via capillarity up the strip, and various reactions take place along it.

[0008] Friesen et al. teaches several zoned devices in which different forms of immunological reactions, such as competitive and sandwich immunoassays can take place.

[0009] These three patents show the general efficacy of test strips based upon fibrous materials, such as paper, in various forms of diagnostics. Many other patents show similar teachings, including U.S. Patent Nos. 3,888,629 (Bagshawe), 4,366,241 (Tom et al.) 4,517,288 (Giegel et al.), 4,668,619 (Greenquist et al.), 4,708,932 (Axen et al.), 4,774,174 (Giegel et al.) 4,786,606 (Giegel et al.), 4,824,640 (Hildebrand et al.), and 4,855,240 (Rosenstein et al.). All of these patents show the general applicability of solid test strips for clinical analysis. Tom et al., for example, at columns 19-26, gives a roster of some of the various analytes which may be assayed by using dry chemistry. Dry chemistry is also taught in connection with the analysis of specific analytes, such as cholesterol (U.S. Patent No. 3,983,005, to Goodhue et al.), human chorionic gonadotropin (U.S. Patent No. 4,496,654 to Katz et al.), hemoglobin (U.S. Patent No. 4,742,002, to Guadagno), and blood type antigens (U.S. Patent No. 4,851,210, to Hewett).

[0010] While analytical test strips of the type described supra are popular, they are not without their problems. Strips made of bibulous materials such as paper, e.g., are subject to wide fluctuations in the quality and properties of the materials used. In addition, impregnation or placement of reagents, such as antibodies on the strip may require processes which lead to degradation of the reagent. For example, if a protein reagent is applied to a test strip in a liquid form, it must of course be dried. Drying may require heat, however, and heat is one of the most notorious inactivators of proteins. Further, due to the inherent absorptive nature of bibulous materials such as paper, it is difficult, if not impossible, to control the eventual distribution of the reagents on the strips when one is attempting to incorporate reagents in a predefined, prescribed, or preferred fashion. Even when extremely stringent criteria of quality control are used, since the capillarity of paper, e.g., can vary not

only from strip to strip but even within a single strip, preparation of a strip always carries a risk. Additionally, fibrous materials are not inert. When assaying for an analyte, it usually happens that a certain amount of it will adhere to the fibers of the strip rather than to reactants, such as antibodies placed on the strip. As a result, interpreting a particular test strip can be very difficult.

[0011] Given the concerns set out supra, as well as others which are not repeated here but are well known to the art, there have been attempts to use other materials. Different fibrous and gel or film materials have been used as supports, but these are not altogether satisfactory for many of the reasons set forth herein. Attention has therefore turned to other materials, including particulate matter such as beads or spheres made of "inert" materials. "Inert" as used herein simply means that the material does not interfere with reactions which are involved in the clinical application under consideration. To say that there are many patents relating to the use of inert particles in clinical and immunological assays is to understate the case. A sampling of some of the U.S. Patents in this area include 4,794,090 (Parham et al.), 4,740,468 (Weng et al.), 4,680,274 (Sakai et al.), 4,657,739 (Yasuda et al.), 4,478,946 (VanderMerwe et al.), 4,438,239 (Rembaum et al.), 4,340,564 (Harte et al.), 4,338,094 (Elahi), 4,201,763 (Monthony et al.), 4,166,102 (Johnson) and 4,059,658 (Johnson). The vast majority of the literature relating to the use of "active" or "loaded" particles, however, is not at all pertinent to this invention. In general, particulate material is used in wet chemistry systems, such as agglutination assays, along the lines of those described supra. A solution containing particles having receptors, such as antibodies bound thereto, is added to a sample being analyzed. If the analyte in question is present in the sample, it binds to the receptor which is itself bound to the particle. As a result of the binding, the particles agglutinate for any of a number of different reasons. Such applications of particle technology are not pertinent to this invention.

[0012] Microparticles present both advantages and disadvantages when used in preparation of analytical devices. The advantages include the uniform size. Also, they increase surface area on which reactions can take place without a need for increased sample volumes. As a result, the speed of reaction can increase. Disadvantages include the possibility of undesirable uncontrolled aggregation of the beads. Also, non specific binding can result in false reactions. When particles are placed in fibrous matrices, they can move, thus confusing results via a "blurring" effect.

[0013] Somewhat more pertinent to this invention are apparatus where particulate material carrying, e.g., a receptor, is contained in a carrier, such as a test strip. The patents to Weng et al. and Yasuda et al. are exemplary of such systems. The problem with the use of particles, such as beads in porous carriers, however, is that the particles, left to themselves, can move in the fibrous matrix, not unlike a ball or marble rolling on a carpet. This tendency to move is exacerbated when a flowing material, such as a liquid, is added to the matrix. The particles then move throughout the device and even off of it with the moving solution front, rendering the test strip useless.

[0014] A different approach to the field of clinical diagnosis attempts to avoid these problems by not using fibrous matrices at all or using fiber in a separate layer, such an approach is exemplified by, e.g., U.S. Patent No. 4,258,001, to Pierce. This patent teaches a dual layer system, where one layer is a structure made of particles bound together by an adhesive. The patent describes the particles as possibly containing a so-called "interactive composition" such as an antigen or antibody. This layer is positioned on a support. Analyte containing liquid passes through the porous particle layer, and the analyte reacts with the interactive composition.

[0015] A system along the lines of that described by Pierce, however, is not without its problems. Adhesives, by their nature, are sticky. Even when dried, a certain amount of "tack" is present which, although small, may not be insignificant with respect to sample analyte. As a result, false binding to adhesive, rather than to the "interactive composition" may occur. In addition, there is some difficulty in the manufacture of uniform arrays of adhered beads, because distribution of the beads may not be uniform, and the drying of adhesive may occur at different rates, depending on parameters, such as thickness of the array.

[0016] Recently, the art has seen some approaches to this problem. U.S. Patent No. 4,916,056, to Brown, III et al., suggests that by selecting an appropriate fibrous matrix and particles of a particular size, one can immobilize the latter in the former. At column 8, lines 60-65 the inventors concede that the reason for this is not known, and review of the disclosure in its entirety gives no information as to any treatment applied to the particles. European Patent Application Number 200 381 also teaches the use of beads with antibodies bound to them in a matrix; however, this disclosure states, while the beads are trapped within the matrix, they are nonetheless mobile. Such a test strip is not completely satisfactory for use in clinical assays.

[0017] One of the consequences of advances in fields related to clinical chemistry, such as immunology, is that many applications of the field which were once deemed sophisticated have now become quite commonplace. One result of this development has been the creation of a home diagnostic market, i.e., a subfield of clinical chemistry in which an individual performs an assay at home, rather than having a health professional perform it. The home user is not trained in the interpretation of clinical parameters, and as such home diagnostic products are generally restricted either to systems where a "yes/no" type of test is used, or one where an unambiguous answer is provided by the test apparatus used. The patent literature shows examples of devices useful in home diagnostics in Brown III et al., U.S. Patent No.

4,916,056, discussed above, and in Valkirs et al., U.S. Patent No. 4,632,901. Both disclosures are drawn in particular to self diagnosis of pregnancy, and point to the need in such systems for an adequate negative control. Indeed, the art has long recognized the desirability and necessity for "on-board" controls in test strips. Examples of disclosures teaching these are 4,649,121 (Ismail et al.), 4,558,013 (Markinovich et al.), 4,541,987 (Guadagno), 4,540,659 (Litman et al.), 4,472,353 (Moore), and 4,099,886 (Olveira). The use of controls on many of these devices shows that they are useful for the skilled practitioner as well as for the home user. The art shows that both "negative" and "positive" controls are used. A "negative" test is one which will inform the user that the test sample does not contain the analyte of interest. In contrast, a true negative "control", as the phrase is used herein, should never give a signal if reagents are operating properly. This is true regardless of whether or not the analyte of interest is present.

[0018] A positive control essentially tells the user that the system and device are functional. Such controls may contain samples of the analyte of interest and the reagent components which are essential to the reaction which must take place to identify analyte in a test sample. Positive controls should always generate a signal when an analytical device containing one is used. If a signal is not generated, then the user has an indication that the apparatus is no longer functional. Thus, positive controls can serve to "date" a test strip by checking the system or reagent integrity. They can also indicate when a test strip or other system component has been stored improperly, or where quality control has not been adequate. Given continued growth in the diagnostic market, positive controls loom as being more and more important.

[0019] As has been indicated supra, among the stresses to which analytical apparatuses are subjected are long periods of storage. Others include improper use or negligent handling. Such stresses may jeopardize the integrity of the apparatus, and may also damage it. It will be clear, of course, that test strips and other analytical apparatus should not be exposed to the environment prior to their intended use in analysis of a sample. Exposure to the environment, e.g., may result in physical harm and/or chemical contamination of the strip. Thus it is clear that these apparatus are desirably protected until used.

[0020] The desirability of protecting the strip must be balanced by the cost of providing it. Given the enormous volume of test strips used by clinical laboratories, physicians offices and so forth, the cost must be kept as low as possible. To that end, many of these devices are packaged cheaply with, e.g., cellophane or plastic, in the form of bags, pouches, etc. Such packaging provides a certain amount of protection, but serve no useful purpose in connection with the use of the strip. Since many of the test strips in the art are used in analysis of infectious materials, and in connection with biological samples such as blood, urine, sputum, feces, and so forth, it is desirable that the protection afforded the test strip also serve to minimize contact of the individual using the strip with the sample. Additionally, since it is desirable for these strips to be configured so that they can be used without any sophisticated knowledge on the part of the user, ideally the casing for the strip should make it easy for the user to employ the device. Also, the protection or casing structure ideally should be configured to act as a "fail-safe" system, if, e.g., too much sample is added to the device. Other desirable features of such a casing include viewing ports or "windows" as well as fluid reservoirs, both of which are described infra.

[0021] While the art does show the use of test strip holders and casings which move in the direction of the above cited goals, none of these achieve all of them. Examples of casings or holders for test strips are seen in, e.g., U.S. Patent Nos. 4,900,663 (Wie et al.), 4,851,210 (Hewett) and 4,331,650 (Brewer et al.), which show the less sturdy type of holder described supra. Frequently these devices are referred to as "test cards", given the nature of their configuration. More substantial holders may be seen in US Patent Nos. 4,943,522, 4,857,453, EP 348 006, GB 2204398 EP 306 772, EP 323605, EP 306336 and EP 183442. None of these devices possess all of the desired properties, e.g., protection, low cost, and ease of use.

[0022] To summarize the art, there are approaches to test strip design which utilize bibulous paper and/or particle technologies. Each of these has advantages and/or problems. The prior art teaches the use of controls, both "positive" and "negative" for use in diagnostic assays. Different types of configurations are available, but a test strip which incorporates a positive control, a negative control, and a testing area is not seen in the art.

[0023] Test strips and devices of the type described herein are frequently enclosed in a casing or housing. These structures permit the actual strip to be used in a manner that ensures optimal results. Such casing or housings should be "inert", i.e., they should not contain any material which will interfere with the assay or test which is carried out on the test strip.

[0024] Important aspects of test strip housing include protection of the user from the fluid or sample being tested. Further, the casing must protect the actual strip from premature contact with other fluids. Such "premature" contact can include contact with a fluid that is not being analyzed, as well as the contact of a zone or region within the strip prior to the desired time of contact. Thus, where a set of sequential reactions or reaction steps must take place, the casing or housing can play an important role in regulating these steps.

[0025] In addition, the type of structure described herein, via appropriate placement of viewing means such as "ports", "windows" or other openings can facilitate the analysis of a test fluid. Also, the housing if constructed in an appropriate manner, will prevent interference with the natural chromatographic nature of the test

strip by inappropriate contact with other surfaces.

[0026] Other features of a housing or casing which must be considered include inertness to the assay. The housing should be made of material which does not interfere with the assay, reagents, or sample. The housing should also be configured in a way that makes it easy to observe the test, without causing problems such as the casting of shadows or otherwise impeding proper viewing of the reaction. In addition, since the amount of sample applied to the test strip will vary from user to user, it is desirable that the holder be configured to prevent overflow or flooding of different sections of the test strip in those situations where excess fluid is added.

[0027] It is an object of the invention to provide a casing or holder for a test strip which protects the test strip itself, simplifies its use by the investigator, and also, surprisingly, helps serves as a fail-safe system to facilitate the take up of sample fluid by the test strip in a controlled manner.

[0028] How these, as well as other aspects of the invention are achieved will be seen from the disclosure which follows.

SUMMARY OF THE INVENTION

[0029] The present invention concerns a casing useful in protecting a test strip, the casing being defined in independent claim 1. A preferred embodiment of the casing according to the present invention is defined in dependent claim 2.

[0030] The present invention also concerns an analytical device comprising a test strip and a casing as defined in independent claim 3.

BRIEF DESCRIPTION OF THE FIGURES

[0031] Figure 1 a is a top view of an embodiment of the casing for the test strip.

[0032] Figure 1 b shows a top view of the bottom of a casing for the test strip.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0033] Test strips are advantageously kept in a casing. Such a casing can not only provide protection to the test strip and safety to the user, but can also facilitate the use of the device in carrying out test analysis, as will be shown from the discussion that follows.

[0034] Referring to Figure 1 a this shows a top view of a casing 40, used in connection with the test device. The top of the casing is an elongated structure made of an inert and tough material such as polystyrene plastic. A rectangular structure with opposing short sides 41 and 41' and opposing longer sides 42 and 42' is provided. Referring to 40, from left to right, the top of the casing contains an application port 43, which is discussed at greater length infra. This port slopes downward from the opening, and provides a point for application of run buffer to the test strip so as to release any reagents contained therein. Moving toward the opposite end of the device a second port 44 is provided, which also slopes downward. This port is positioned over the three zones of the strip device, i.e., the negative control read , and positive control. In practice, the sample to be analyzed, as well as possible other reagents, are added here. Again, the port slopes downward. The angle at which the walls of the port slope is selected so as to minimize shadowing, which can adversely affect interpretation of results. In the embodiment shown, the arrow 45, "R" 46, and "C" 47 are presented to aid in the use of the device. The arrow indicates where the sample to be analyzed is to be added, and "R" and "C" stand for the "read" or test and "control" or positive zones, respectively. Toward the end of the apparatus the shaded portion is an optional design embodiment.

[0035] A plurality of tabsets or joining means 48 protrude from dorsal side of the top of the casing, and are positioned to engage corresponding tabsets (52) in the bottom portion of the casing. Dotted lines 49 and 49' show that the underside of this portion of the casing is recessed to create what is in effect a slightly smaller rectangle within a larger one. The bottom portion of the device, in figure 1 b described infra depicts the inner and outer walls of that portion of the structure more clearly, and a parallel configuration is present in the top portion, which engages the bottom portion.

[0036] Referring now to Figure 1 b, this is an open top view of the bottom portion 50 of the casing. This is made of the same material as the top portion, and has the same geometrical configuration. A pair of longitudinal bars 51 is present on the bottom of the casing and, together with a plurality of pairs of tabsets 52 define a guide for positioning of the test strip therein and also serve to hold the strip off the bottom of the housing. At least some of these tabsets combine with parallel tabsets in the top portion of the casing to form a joined structure when the top and bottom of the casings fit together. The bottom has, around its perimeter an inside wall 53 and an outside wall 54, which align with equivalent structures 49 and 49' in the top of the casing 40.

[0037] An important feature of the housing top is that it is configured so that the four walls of port 44 do not quite touch the test strip positioned therein. The result is that a small capillary space is created which in turn allows port 44 to retain sample and other reagents, and effectively "meters" application thereof to the test strip. Also, because the casing material does not directly contact the test strip, there are no uncontrolled or unrecognized effects on the properties of the test strip itself.

[0038] A similar type of structure results from the interpolation of tabsets protruding from the top and bottom of the casing. When these tabsets interact with each other, they effectively seal the enclosed strip element, resulting in formation of at least two reservoirs which retain excess fluid. To elaborate, it will be seen in Figure 1 b

that hollow spaces 55 and 55' extend over the length of the housing along the length of the test strip. These spaces can hold liquid and, if too much is added at either of ports 43 or 44, this can result in overflow of the strip device. The sealing of casing parts 40 and 50 creates discrete overlfow compartments by interaction of the tabsets, however, resulting in retention of the excess fluid (such as sample and reagents) in the compartment immediately adjacent to the application point until the test strip is ready to absorb it. In effect, this interaction results in another metering means, insuring that liquid applied to the strip device enters the strip only at the desired location.

[0039] The top and bottom portions are fitted together and sealed after the actual test device or apparatus is positioned in the bottom portion thereof. The manner of sealing is up to the artisan. Examples of various ways the sealing can be accomplished are adhesives, application of heat, snap fitting or via sonic energy. It is also conceivable, though not likely, that the casing will be constructed so that the top and bottom portions can be detached and the test strip removed.

Claims

1. Casing useful in protecting a test strip, said casing comprising

   (i) a first, elongated top member (40) defined by two pairs of opposing sides (41, 41', 42, 42'), a top and a bottom, wherein said top member (40) has at least two openings (43, 44) positioned in longitudinal relationship to each other therein, wherein the second opening (44) is defined by two pairs of opposing sides, at least the pair of which parallel to the longitudinal direction of the top member (40) slopes from top to bottom to define a flow path for application of a liquid, at least said pair terminating in a ridge means, said top member further comprising on its bottom at least one pair of means (48) for engaging said first, top member (40) with a second, bottom member (50), and
   (ii) a second, bottom member (50) defined by two pairs of opposing sides, said bottom member having a longitudinal cavity for reception of a test strip, said second member (50) further comprising at least one pair of means (52) for engaging said first, top member (40),

   wherein said means for engaging (48) on said first member (40) and said means for engaging (52) on said second member (50) form at least two discrete reservoirs for reception of fluid when engaged.

2. The casing of claim 1, wherein said first member (40) comprises a depression at an end thereof opposite to the end at which one of said openings (43, 44) is positioned.

3. Analytical device comprising a test strip and a casing according to claim 1 or 2.

Patentansprüche

1. Gehäuse, das zum Schutz eines Teststreifens brauchbar ist, umfassend

   (i) ein erstes, längliches oberes Element (40), definiert durch zwei Paare gegenüberliegender Seiten (41, 41', 42, 42'), eine Oberseite und eine Unterseite, wobei das obere Element (40) wenigstens zwei Öffnungen (43, 44) aufweist, die darin längsweise zueinander angeordnet sind, wobei die zweite Öffnung (44) durch zwei Paare gegenüberliegender Seiten definiert ist, wenigstens dasjenige Paar, das parallel zur Längsrichtung des oberen Elements (40) verläuft, von oben nach unten geneigt ist, um einen Fließweg zum Auftragen einer Flüssigkeit zu definieren, wenigstens dieses Paar in einer Grateinrichtung endet, wobei das obere Element auf seiner Unterseite des weiteren wenigstens ein Paar Hilfsmittel (48) zum Einrasten des ersten, oberen Elements (40) mit einem zweiten, unteren Element (50) umfaßt, und

   (ii) ein zweites, unteres Element (50), definiert durch zwei Paare gegenüberliegender Seiten, wobei das untere Element einen in Längsrichtung verlaufenden Hohlraum zur Aufnahme eines Teststreifens aufweist, das zweite Element (50) des weiteren wenigstens ein Paar Hilfsmittel (52) zum Einrasten des ersten, oberen Elements (40) umfaßt,

   wobei die Hilfsmittel zum Einrasten (48) am ersten Element (40) und die Hilfsmittel zum Einrasten (52) am zweiten Element (50) wenigstens zwei diskrete Reservoirs zur Aufnahme von Flüssigkeit bilden, wenn sie eingerastet sind.

2. Gehäuse nach Anspruch 1, wobei das erste Element (40) eine Vertiefung an seinem einen Ende umfaßt, das dem Ende gegenüberliegt, an dem sich eine der Öffnungen (43, 44) befindet.

3. Analytische Vorrichtung, umfassend einen Teststreifen und ein Gehäuse nach Anspruch 1 oder 2.

Revendications

1. Boîtier utile pour protéger un ruban de test, ledit boî-

tier comprenant:

(i) un premier élément allongé (40), supérieur, défini par deux paires de côtés opposés (41, 41', 42, 42'), un sommet et une base, ledit élément supérieur (40) présentant au moins deux ouvertures (43, 44) disposées en relation longitudinale l'une par rapport à l'autre, la deuxième ouverture (44) étant définie par deux paires de côtés opposés dont au moins la paire qui est parallèle à la direction longitudinale de l'élément supérieur (40) forme une pente du sommet à la base pour définir un parcours d'écoulement en vue de l'application d'un liquide, au moins ladite paire se terminant en un moyen de crête, ledit élément supérieur comprenant en outre à sa base au moins une paire de moyens (48) destinés à permettre l'engagement dudit premier élément supérieur (40) par un deuxième élément de base (50), et
(ii) un deuxième élément de base (50) défini par deux paires de côtés opposés, ledit élément de base présentant une cavité longitudinale pour réception d'un ruban de test, ledit deuxième élément (50) comprenant en outre au moins une paire de moyens (52) destinés à engager ledit premier élément (40) supérieur,

dans lequel lesdits moyens d'engagement (48) prévus sur ledit premier élément (40) et lesdits moyens d'engagement (52) prévus sur ledit deuxième élément (50) forment au moins deux réservoirs distincts pour réception d'un fluide lorsqu'ils sont engagés.

2. Boîtier selon la revendication 1, dans lequel ledit premier élément (40) comprend un creux à son extrémité opposée à l'extrémité sur laquelle l'une desdites ouvertures (43, 44) est disposée.

3. Dispositif analytique comprenant un ruban de test et un boîtier selon les revendications 1 ou 2.

FIG. 1A

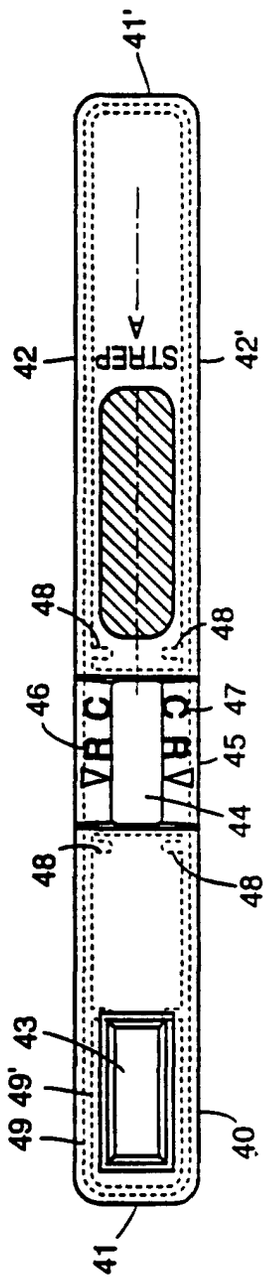
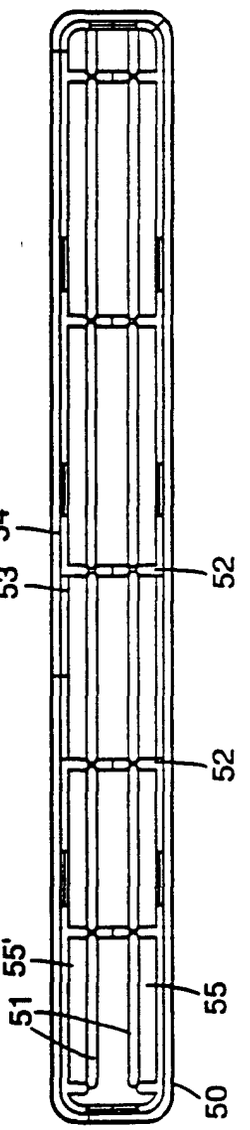

41'
42
42'
STREP
48
48
46
47
45
44
48
48
43
49'
49
40
41

FIG. 1B


54
53
52
52
55'
51
55
50